DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 22, 2015

Penumbra, Inc.
Michaela Mahl
Senior Manager, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

Re: K142870
Trade/Device Name: Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 24, 2015
Received: April 27, 2015

Dear Ms. Mahl:

This letter corrects our substantially equivalent letter of May 26, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142870

Device Name
Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)

Indications for Use *(Describe)*
The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

Not for use in the coronaries or the neurovasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1 510(k) Summary

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System).

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

1.2 Sponsor Contact Information

Michaela Mahl
Senior Manager of Regulatory Affairs
Phone: (510) 748-3288
FAX: (510) 217-6414
Email: michaela.mahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 26, 2015

1.4 Device Trade or Proprietary Name

Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)

1.5 Common/Usual Name

Embolectomy Aspiration System

1.6 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Embolectomy catheter
Regulation Number:	21 CFR § 870.5150
Product Code:	DXE

1.7 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K121917 [19Sep2012]	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra, Inc.

1.8 Predicate Comparison

System Name	**Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)**	
Device	**Predicate Device**	**Subject Device**
510(k) No.	K121917	K142870
Classification	Class II, DXE	SAME
Indication	The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial system. Not for use in the coronaries, the venous system or the neurovasculature.	The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature.
Materials	Biocompatible, commonly utilized for interventional devices	SAME plus additional material compositions
Coating	Hydrophilic coating	SAME
Effective Length	Appropriately sized for the target vasculature	SAME plus shorter & longer lengths
Proximal OD & ID		SAME with larger diameters
Distal OD & ID		SAME with larger diameters
Packaging Materials	Commonly used materials for medical devices	SAME
Packaging Configuration	Individual	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	SAME

1.9 Device Description

The Penumbra Embolectomy Aspiration System's (INDIGO™ Aspiration System) fundamental mechanism of action is aspiration. Aspiration draws the embolus or thrombus into the Aspiration Catheter to remove the embolus or thrombus from the body. All Separators function to break up the clot inside of the catheter to make it more amenable to removal from the body via aspiration. The Aspiration Catheter and Separator are available in multiple configurations. The devices are provided sterile, non-pyrogenic, and intended for single use only.

1.10 Indications for Use

The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature.

1.11 Summary of Non-Clinical Data

Included in this section are descriptions of the testing, which substantiates the safe and effective performance of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) as well as its substantial equivalence to the predicate devices:

- Biocompatibility / Pyrogenicity
- Design Verification (Bench-Top Testing)
- Animal Study

For the subject Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) all established requirements and acceptance criteria were met.

1.11.1 Biocompatibility Testing

Biocompatibility is established for the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) devices based on tests selected in accordance with EN ISO 10993 -1 guidelines (Biological Evaluation of Medical Devices) for limited duration (<24 hours), external communicating devices, contacting circulating blood and limited exposure (≤ 24 hours), surface contact, skin contact devices. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. In summary the following below listed biocompatibility testing was leveraged from predicate devices. Additionally, cytotoxicity, sensitization, and irritation testing was performed on the Aspiration Tubing for the subject device.

Test	Method	Result
Cytotoxicity	L929 MEM Elution Test	Non-Toxic
Sensitization	Kligman Maximization	Non-Sensitizing
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test	Non-Irritant
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test	Non-Toxic
Haemocompatibility	Complement Activation	No greater biological response than corresponding control
	Hemolysis	Non-Hemolytic
	Coagulation - PT	No Statistical Difference from control
	Coagulation - PTT	No Statistical Difference from control
	In vivo thrombogenicity	Non-Thrombogenic
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test	Non-Pyrogenic
Genotoxicity	Mouse Lymphoma Mutagenesis Assay - ISO	Non-Mutagenic
	Ames Test	Non-Mutagenic
	Micronucleus Assay - ISO	Non-Clastogenic

1.11.2 Bench-top Testing

Testing was based on the design specifications, risk analysis and available guidance documents. These guidance documents include:

- Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (FDA – 1995)
- EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters – Part 1: General Requirements

Devices used for mechanical testing were assembled and packaged in the controlled production environment and sterilized twice using an ethylene oxide sterilization cycle.

The physical and mechanical properties of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) devices were assessed using standard test methods and pre-determined acceptance criteria. All established acceptance criteria were met. The following tests were performed:

- Visual & Dimensional Test
- Friction Test
- Pouch Seal Strength Test
- Flow Rate Test

- Tensile Strength Test
- Bond Strength Test
- Hub Air Aspiration Test
- Burst Test
- Particulate Test
- Coating Integrity Test
- Flexibility Test
- Kink Resistance Test
- Ovalization Resistance Test
- Elongation Test
- Corrosion Test
- Torsion Test
- Simulated Use Test
- Leak Test
- Clot Removal Test
- Vacuum Collapse Test
- Trackability Test

The results of the tests appropriately address the physical and mechanical performance expectations of the devices. This is further supported by the surgical handling and performance results reported in the in vivo study. Based on these overall results, the physical and mechanical properties of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) devices are acceptable for the intended use and substantially equivalent to the predicate devices.

1.11.3 Animal Study

An animal study was conducted to evaluate the safe use of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) devices. The studies concluded that:

- No vessel injury was noted on the final angiograms following the vessel response procedure.
- No abnormal gross or histology findings were noted in test vessel segments.
- The use of the devices resulted in no significant vascular response in these experimental conditions.

1.11.4 Summary of Substantial Equivalence

The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.